

Remarks

This Response and Interview Summary is submitted in view of the office action mailed on October 16, 2008, and the telephonic interview conducted with the Examiner in the case on December 11, 2008. That interview is also summarized herein.

Status of All of the Claims

Below is the status of the claims in this application.

1. Claim(s) pending: 68-104.
2. Claim(s) cancelled: 1-67.
3. Claim(s) added: None.
4. Claims withdrawn from consideration but not cancelled: None.

Examiner Interview

Applicant acknowledges and thanks the Examiner for the interview conducted on December 11, 2008. During that interview, the 112 and prior art rejections were discussed. Applicant pointed to various portions of the specification which provide support for the claims rejected under 112, as cited in the Response to Final Action submitted in this case on December 21, 2007. It was agreed that Applicant would submit specific references to the specification in response to the 112 rejections. The cited prior art was also generally discussed, and Applicant pointed out that the cited art did not disclose the use of a solid, transparent or translucent material to allow the user to view the movement of a blood sample from an edge, sample application port through the capillary channel to a fill line. Applicant represented that all of the pending claims have the requirement of both the solid, transparent or translucent material and the fill line.

Response to the 112 Rejections

The claims have been rejected for an asserted failure of the disclosure to disclose a “fill line”. In response, Applicant submits the following comments and cites to the specification in support of the claims, including specific reference to the disclosure of a “fill line” as called for in the claims. Applicant therefore believes that the new claims are sufficiently supported under §112.

General support for the claims, including the provision of a “fill line”, is found throughout the specification and the drawings. Attention is directed to the Abstract (lines 11-15), the Figures (particularly Figures 1, 3i and 5), and the disclosure found at column 1, line 61 to column 2, line 14; column 4, lines 1-48; and column 8, line 26 to column 9, line 9. In addition to these general portions of the specification, support for the term “fill line” is exemplified by the following passages:

Abstract, lines 11-15:

“The roof of the capillary test chamber includes a transparent or translucent window which operates as a ‘fill to here’ line, thereby identifying when enough test sample (a liquid sample, such as blood) has been added to the test chamber to accurately perform a test.”

Col. 1, lines 63-67:

“The second new feature is a transparent or translucent window which operates as a ‘fill to here’ line, thereby identifying when enough test sample (a liquid sample, such as blood) has been added to the test chamber to accurately perform a test.”

Col. 8, line 63 to col. 9, line 4:

“it is possible for a user of reasonable visual acuity to determine if the window is entirely full of the sample. By choosing the window dimensions as just stated it is possible to provide feedback for the user of the test strip that the strip has been sufficiently dosed with a test sample. Visual confirmation of the window being full provides assurance that a sufficient area of the working electrode is covered

with sample and that a sufficient part of the counter or reference electrode 6 is also covered.”

Applicant submits that it is apparent that the application sufficiently discloses the concept claimed herein, that being the provision of a line demarcated on a test strip which indicates to where the blood sample must fill in order to conduct a test.

Response to the Prior Art Rejections

All of the claims of the present application include the combination of the solid, transparent or translucent viewing material and a fill line. These limitations are contained in each of the independent claims 68, 82 and 96. These claims describe a capillary-fill, electrochemical test strip in which the movement of a blood sample to a fill line can be visualized through the solid, transparent or translucent material to provide confirmation to the user that sufficient blood has been dosed to the strip, and has reached the required test area, such that the test results can be accurate.

All of the cited references have a common failing with respect to the present claims - a blood sample can not be viewed through a solid, transparent or translucent material as the sample fills a capillary channel inwardly from the edge of a test strip to a fill line:

- Diebold ‘999 includes a capillary channel defined by a cutout 49 sandwiched between top and bottom layers; there is no indication that either of the outer layers is transparent or translucent, or that there is any kind of fill line, and indeed the capillary channel is shown as being hidden (see dashed lines in Fig. 6) by the outer layers.
- Hodges ‘102 and ‘420 show sandwich-type test strips in which the interior, circular chamber is hidden by the outer layers and consequently there is no fill line.

- Charlton '031 shows a test strip having a base 36 and a lid 46, with the lid embossed to form a concave space 48 constituting the capillary channel. Charlton does not identify any solid portion(s) of the base or lid as being transparent or translucent, and does not identify a fill line.
- Ikeda '895 discloses a sandwich-type test strip with top and bottom layers 6 and 9 and an interior chamber 11-11b. There is no indication that any portion of the layers 6 or 9 is transparent or translucent, and there is no fill line.
- Yoshioka '103 has a similar sandwich-type design, and fails to show that any portion of the outer layers 1 or 4 is transparent or translucent or that there is a fill line.
- Seshimoto '445 discloses a device including a bottom plate 21 and a top plate 18, with testing electrodes 11a-11c received in an interior passage 14. Sample is received at top opening 12 and then directed down through passage 13 to the interior 14. There is nothing in Seshimoto '445 to suggest that any part of plate 21 or plate 18 is transparent or translucent to allow viewing of the sample as it moves along interior passage 14, or that there is a fill line.
- Columbus '457 provides a device in which sample is received through a top opening 42 or 42' and conveyed through a capillary channel defined by surfaces 34 and 36. There is no indication that the top 30 (including surface 34) or the bottom 32 (including surface 36) is transparent or translucent, or that there is a fill line.
- Galen et al. '949, and '692 disclose top-dosing strips with openings 6, 7 and 11 extending from a top substrate through to a bottom substrate. There is no solid,

transparent or translucent portion to allow blood to be visualized as it fills a capillary channel, and no fill line to indicate when sufficient filling has occurred.

In comparison, the present invention provides a uniquely advantageous design for a capillary fill test strip in which the filling of the strip is viewable to show if adequate filling has occurred to conduct a test. Test strips which do not adequately fill can produce inaccurate results. The present invention provides an elegant solution to this problem by allowing the users to visually watch the blood fill the test strip, and to readily determine whether the blood makes it to the fill line – the indicator when at least enough blood has been added.

Further consideration of the application and allowance of claims 68-104 is respectfully requested. The examiner is requested to contact the undersigned by telephone if it appears that issues may thereby be more readily resolved leading to allowance of this application.

Respectfully submitted,

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